REMARKS

Applicants respectfully request that the foregoing amendments be made prior to examination of the present application. The specification has been amended to recite the chemical name for the trade name Eudragit® RS 30 D. Applicants have attached hereto as Exhibit 1 a reference reciting the chemical name of Eudragit® RS 30 D. Claim 6 is directed to this embodiment and new dependent claims 12-19 find support from original claim 6. Claim 5 and new dependent claim 11 overcome the rejection under 35 USC § 112 for indefiniteness.

Claim Rejections Under 35 USC § 102(b)

Applicants traverse the rejection of claims 1-10 as being anticipated by US Patent No. 5,672,360 ("Sackler") for the following reasons. Although Sackler discloses a composition having Eudragit® RS 30 D and talc, Sackler does not suggest the use of hydrophobic silica.

Talc is not hydrophobic silica, rather it is magnesium silicate having the following formula: $Mg_6 (Si_2O_5)_4(OH)_4$ (See Exhibit 2). Silica or "colloidal silicon dioxide" has the formula SiO_2 (See Exhibit 3). Hydrophobic silica is a micro-fine silica treated with an organic silicon fluid (See Exhibits 4 and 5). Therefore, the pending claims are novel over Sackler.

Talc and silica do not posses the same physical properties. In Sackler talc is used as a conventional lubricant or anti-tacking agent. (See for example Column 28, line 52). By contrast, silica is usually used to stabilize emulsions and as a thixoptropic, thickening and suspending agent (See Exhibit 3).

Sackler teaches sustained release morphine sulfate granules that provide an analgesic effect for at least 24 hours and initial rapid absorption. A difference between the claimed granules and the granules of Sackler is that the sustained release coating, which in the present invention, does contain hydrophobic silica, whereas in Sackler, it does not. This difference, as explained in the specification, results in improved functional differences.

Accordingly, the microgranules of the present invention exhibit the advantage of not requiring a protective coating of the sustained release layer, contrary to Sackler. (See page 4, lines 24-26 of the present specification and column 15, lines 53-54 of Sackler.)

Moreover, due to the addition of the hydrophobic silica to the sustained-release coating, it is not necessary to subject the microgranules to a very lengthy heat treatment (longer than 24 hours) as in Sackler to improve the structure of the sustained release layer. (See page 4, lines 26-30 of the present specification and column 15, lines 55-58 of Sackler.)

Accordingly, the use of a particular silica, i.e. hydrophobic silica, and not talc, surprisingly allows those two supplementary steps to be not necessary and therefore simplifies the process for preparing granules. Furthermore, it allows sustained release of sulfate morphine and covers over 24 hours. (See Example 1, page 10, lines 9-10 of the present specification.)

Applicants urge that based on the teachings of Sackler, one of ordinary skill in the art would not be motivated to replace talc with hydrophobic silica since the functions for these two excipients are different. Therefore, applicants urge that Sackler does not anticipate or render obvious the present invention.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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